



MAR 27 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Dr. P Armstrong  
Regulatory Affairs  
Randox Laboratories, Ltd.  
Ardmore, Diamond Road,  
Crumlin, Co. Antrim,  
United Kingdom,  
BT29 4QY

Re: K000469  
Trade Name: Complement C3  
Regulatory Class: II  
Product Code: CZW  
Dated: January 27, 2000  
Received: February 11, 2000

Dear Dr. Armstrong:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

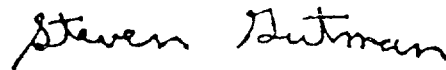
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

10(k) Number (if known):

~~NOT KNOWN~~  
K000469

Device Name:

COMPLEMENT C3

**Indications For Use :**

The Randox Laboratories Ltd. Complement C3 Test Kit is an *in vitro* diagnostic reagent for the quantitative determination of Complement C3 in serum. The method is an immunoturbidimetric assay in which a sample is diluted and reacted with a buffer containing antibody specific for human Complement C3. The absorbance of the resulting turbid solution is proportional to the concentration of C3 in the sample. By constructing a standard curve from the absorbance of the standards, the C3 concentration of the sample can be determined. The measurement of Complement C3 in serum is important in determining inherited or acquired deficiencies whilst, conversely, levels may rise in a variety of inflammatory and necrotic disorders as part of the acute-phase plasma protein response.

This Application Sheet has been developed for the Hitachi 717 Analyser and must be used by suitably qualified laboratory personnel under appropriate laboratory conditions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)

Division of ~~Medical Devices~~ ~~Medical Devices~~ ~~Medical Devices~~

510(k) Number

K000469

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐  
(Optional format 1-2-96)